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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,400	05/09/2001	William L. Trepicchio	GFN-5405CP	5404

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EXAMINER

WHISENANT, ETHAN C

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,400

Applicant(s)

TREPICCHIO ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 1-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 43-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

ELECTION/RESTRICTION

1. Applicant's election of Group II (**Claims 43-47**) and **squamous cell carcinoma antigen 2** in the response filed 11 APR 03 is acknowledged. Claims 1-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. It is noted that the applicant has not traversed the restriction requirement, distinctly and specifically pointing out any supposed errors in the restriction requirement, therefore, this election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement has been reconsidered, is deemed proper and is therefore, herein made **FINAL**.

However upon reconsideration and in consultation with multiple SPEs, an additional restriction requirement of Group II needs to be imposed, see below.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group II(a) : Claim 43-44, Drawn to a method of treating a subject afflicted with psoriasis or a TH1-associated condition which method comprises providing to cells of the subject afflicted with psoriasis or a TH1-associated condition a protein corresponding to a marker which marker is squamous cell carcinoma antigen 2, classified in **Class 514, subclass 2**.

Group II(b) : Claim 45, Drawn to a method of treating a subject afflicted with psoriasis or a TH1-associated condition which method comprises providing to cells of the subject afflicted with psoriasis or a TH1-associated condition an antisense oligonucleotide corresponding to a marker which marker is squamous cell carcinoma antigen 2, classified in **Class 514, subclass 44**.

Group II(c) : Claim 46-47, Drawn to a method of inhibiting psoriasis or a TH1-associated condition in a subject at risk of developing psoriasis or a TH1-associated condition which method comprises inhibiting or enhancing the expression of a gene corresponding to a marker which marker is squamous cell carcinoma antigen 2.

- 3.** The inventions are distinct, each from the other for the following reasons.

Inventions II(a) and II(b) is/are drawn to two independent and distinct methods of treating a subject afflicted with psoriasis or a TH1-associated condition. In the first, an oligonucleotide is utilized while in the second a protein is utilized. The polynucleotide and polypeptide products of groups I and II can be shown to be distinct, each from the other. Although the polynucleotides and polypeptides are said to be related in that the polynucleotide of Group I and the protein of Group II correspond to the same marker (i.e. squamous cell carcinoma antigen 2), they are distinct inventions because polynucleotides and polypeptides are physically and functionally distinct chemical entities. The oligonucleotide of group I and the protein of group II are structurally and functionally distinct from each other. Proteins are composed of amino acid subunits while nucleic acids are composed of nucleotide subunits. Each group will require a non-coextensive literature search.

Note that the invention of **Group II(c)** is a separate and distinct invention from that recited in **Group II(a) and II(b)** in that it does not require that oligonucleotides or proteins be provided.

- 4.** Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature, restriction for examination purposes as indicated is proper.

- 5.** Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

- 6.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general

Application/Control Number: 09/852,400

Page 4

Art Unit: 1634

nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'EWH', is positioned above the printed name.

**ETHAN WHISENANT
PRIMARY EXAMINER**